

### **DETAILED ACTION**

Examiner acknowledges the reply filed September 28, 2010.

#### ***Response to Arguments***

Applicant's arguments regarding the Skardon reference are persuasive, therefore the previous rejection has been withdrawn, and a new grounds of rejection is provided, below. Arguments regarding Iliff are not found persuasive, and are addressed below via clarification of the rejection, as well as in the rejection under 35 U.S.C. 112. Claims 1 and 11 are further rejected under 35 U.S.C. 112, 2nd paragraph, and remain rejected under 35 U.S.C. 101, see below.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 9, 10, 18 and 21 are rejected under 35 U.S.C. 101, since the claims when considered as a whole are held to claim an abstract idea or collection of mental steps, which is ineligible subject matter. In particular, Applicant has claimed a "computer readable medium" on which data is stored. However, the essential steps of the method, such as creating diagnoses, preparing test proposals, and selecting comparable anamneses are not tied to any particular machine or apparatus. Instead, the involvement of a machine (in this case computer readable medium) is for mere data storage. As such, numerous steps of the claimed method are mental

steps or steps performed by a human under their broadest reasonable interpretation. To overcome such a rejection, the Examiner suggests positively claiming a processor performing the method steps.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9 – 11, 14 – 18, and 21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the claims contain the term “and/or” in numerous places. It is unclear what the Applicant regards as the invention since the limitation elements *may* be in the alternative or *may* all be required. The broadest reasonable interpretation of this term renders the elements of the limitation in the alternative, and therefore this interpretation has been adopted in examining the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1, 9 – 11, 14 – 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff U.S. Patent No. 5,868,669, in view of Marchosky U.S. PGPub No. 2002/0029157 A1, further in view of Fey et al. U.S. PGPub No. 2002/0038227 A1 ("Fey").**

Iliff discloses a method for recording and analyzing diseases and their causes and for establishing appropriate therapy proposals comprising:

a) preparing at least one set of anamnesis questions, wherein the anamnesis questions include questions relating to the time and/or cause of the occurrence, the severity of, symptoms of an allergic disease and the environmental exposure of a patient, and storing this set in a data memory in a computer-readable media (Iliff column 35 lines 51 – 57, column 36 lines 11 – 49, column 39 lines 1 – 11 questions are presented to the user to collect information about medical history and identifying causes, symptoms, and the severity of symptoms. The term "and/or" in this limitation has been interpreted to mean the elements are in the alternative, and therefore time is not required),

b) preparing a set of data relating to the causes of diseases, and storing this set in a data memory in a computer-readable media, wherein the data is continuously revised and extended (Iliff column 12 lines 24 – 60, column 35 lines 25 – 64 question sets used to collect medical history data and to narrow diagnoses are retrieved and presented to the user based in part on the user's possible condition. The question sets are continuously revised with new questions as new diseases are discovered),

c) providing a computer program which selects and presents anamnesis questions according to a predetermined set of rules (Iliff column 12 lines 24 – 60, column 35 lines 25 – 64,

column 36 lines 1 – 49 question sets to collect medical history data and to narrow diagnoses are retrieved and presented to the user based in part on the user's possible condition.),

d) recording the answers to the anamnesis questions in a computer-readable media, wherein within the framework of the anamnesis questions preliminary information is recorded which includes at least the age and gender of a patient and optionally one or more affected organs and/or other diagnosed illnesses, and wherein the answers are at least partly predetermined in discrete selection steps (Iliff column 30 lines 3 – 30, column 35 lines 51 – 57, column 36 lines 11 – 49, column 39 lines 1 – 11 answers to questions are recorded in a patient medical history file which includes age and gender data, as well as information identifying the anatomic system, causes of illness, and severity of symptoms experienced. The term “and/or” in this limitation has been interpreted to mean the elements are in the alternative.),

Regarding steps (e), (f), and (g), Iliff discloses scoring responses to questions and summing the scores until thresholds are reached in the diagnosis process (Iliff column 5 lines 36 – 57, column 39 lines 6 – 67, column 40 lines 1 – 61). The thresholds are set to identify different causes of medical issues, which are diagnoses, and the determined causes are ranked based on scores and exceeded thresholds (Iliff column 39 lines 5 – 67, column 40 lines 1 – 61). While Iliff positively discloses scoring question responses and using the scores for diagnoses, it is submitted by the Examiner that numerous equivalent diagnosis methods are known aside from scoring responses to questions. The use of a scoring system is an obvious variant of other methods such as decision tree algorithms that use responses to questions or entered data to filter through possible diagnoses and arrive at the most probable diagnosis.

g) creating a set of possible diagnoses using the criterion of whether the total point values for specific groups of answers and/or the entire anamnesis exceed a predeterminable threshold

value and preparing a proposal for the allergens to be tested to further narrow down the diagnosis (Regarding (g) through (k) Iliff column 24 lines 29 – 42, column 36 lines 11 – 33, column 39 lines 5 – 67, column 40 lines 1 – 61, column 41 lines 11 – 67, column 42 lines 1 – 48 probable causes and diagnoses are identified by the scores and exceeded thresholds. The system further narrows its list of probable causes including allergies by asking additional questions which comprise additional tests. Probable causes and conditions are ranked by the computer program based on scores of questions, which comprises a preparation and display of diagnosis proposals. Furthermore, the system prepares and outputs suggestions to the patient including additional tests to perform to confirm the probable diagnosis, suggestion medical actions to be taken such as treatment or visits to a physician, and stores this data with other patient data in the system database. The term “and/or” in this limitation has been interpreted to mean the elements are in the alternative, and therefore the display of therapy proposals is not required).

Iliff discloses a computerized, knowledge based medical diagnostic and treatment system. The system diagnoses and provides advice to patients based on collected medical history data regarding symptoms, diseases, and medication data. Questions regarding different medical conditions and symptoms are presented to the user, and answers are scored for diagnostic purposes. Iliff fails to disclose to disclose data stored in anonymized form, and the preparation of therapy proposals and proposals of additional tests to be conducted. However Marchosky a reference in an analogous art of computerized medical diagnosis and care discloses collecting patient data through a plurality of questions which are scored and stored in anonymous patient records, analyzing the score, and presenting probable diagnoses coupled with therapy and test recommendations (Marchosky paragraphs 0038, 0040, 0054, 0055, 0057, 0063, 0074 – 0083, 0092, 0093, 0099). It would have been obvious to one of ordinary skill and creativity in the art

to modify the system and method of Iliff with the aforementioned features of Marchosky, Marchosky teaches the necessity of anonymous computer records, and seeks to improve computerized medical care by including at least diagnosis, treatment, and additional test proposals.

Furthermore, Iliff and Marchosky disclose using anonymous patient records for medical population studies (Marchosky paragraph 0055), yet fail to disclose *selecting comparable data based on a user's medical history*. However, Fey a reference in an analogous art of health screening and diagnosis discloses a networked health screening system that queries a database of a population for similar trends and results (Fey paragraphs 0025, 0065, 0094). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the diagnosis system of Iliff and Marchosky with the population database of Fey, since Fey states that having more current information available to the medical community provides leaps forward in preventative care and early intervention, and the population information can help better develop risk assessments (Fey paragraph 0094).

Finally, the systems of Iliff, Marchosky, and Fey are not limited in scope to any particular disease, and are even adaptive to newly discovered diseases (Iliff column 12 lines 24 – 35). Allergies are disclosed in and discussed throughout the reference as a disease monitored within the scope of the invention (Iliff column 36 lines 11 – 33, column 47 lines 6 – 15). Marchosky discloses collecting patient data regarding allergies (Marchosky paragraphs 0005, 0038, 0039), yet Iliff, Marchosky, and Fey fail to explicitly disclose using the diagnosis and treatment system to diagnose allergies and recommend allergens to test. However, it would have been obvious to one of ordinary skill and creativity in the art of medical diagnoses to adapt the inventions of Iliff, Marchosky, and Fey for the diagnosis and treatment of allergies. Allergic disorders are well

known diseases that affect a significant portion of the population, and are known to have a wide range of identifying symptoms. One of ordinary skill and creativity would have sought to use a system that was not limited to a particular disease to treat allergies, especially since Iliff and Marchosky both disclose the detection of allergies as causes for symptoms, and collect allergy data for patients (citations above). There is nothing in the reference that teaches away from diagnosing and treating allergies, only portions cited above the support the adaption of the invention for such a purpose. Additionally, modifying the additional test proposals of Marchosky would naturally result in allergens to be tested when the invention is used for diagnosing allergies, since allergens provide positive identification of an allergic disorder, just as tests for other diseases would provide positive identifications of those diseases.

9. A method according to Claim 1, wherein step g) includes the comparison of the obtained set of answers with other sets of answers which have been obtained from earlier anamneses (Fey paragraphs 0025, 0094).

10. A method according to Claim 1, wherein contraindications are recorded prior to the preparing of therapy proposals (Iliff column 13 lines 14 – 29, column 25 lines 1 – 30 data regarding medication history and experiences are collected and recorded in the medical history file).

18. A method according to Claim 1, wherein contraindications are recorded prior to the preparing of therapy proposals within the framework of d) (Iliff column 13 lines 14 – 29, column

25 lines 1 – 30 data regarding medication history and experiences are collected and recorded in the medical history file).

21. A method according to Claim 1, wherein the computer program has a scale valuation and combination of the scale valuations of individual answers for the analysis of the recorded data (Iloff column 39 lines 6 – 67, column 40 lines 1 – 61).

Claims 11, and 14 – 17 are rejected on substantially the same basis as claims 1, 9, 10, 18, and 21.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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3769

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